

## § 121.9

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for each select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 121.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

### § 121.9 Responsible official.

(a) An individual or entity required to register under this part must designate an individual to be the responsible official. The responsible official must:

(1) Be approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General;

(2) Be familiar with the requirements of this part;

(3) Have authority and responsibility to act on behalf of the entity;

(4) Ensure compliance with the requirements of this part;

(5) Have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan; and

(6) Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

(b) An entity may designate one or more individuals to serve as an alternate responsible official who acts for the responsible official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official.

(c) The responsible official must report the identification and final disposition of any select agent or toxin

contained in a specimen presented for diagnosis or verification.

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or email: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), *Bacillus anthracis*, *Burkholderia mallei*, *Burkholderia pseudomallei*, classical swine fever virus, foot-and-mouth disease virus, virulent Newcastle disease virus, rinderpest virus, and swine vesicular disease virus. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(2) To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.

(3) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(d) The responsible official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61332, Oct. 16, 2008; 77 FR 61078, Oct. 5, 2012]

### § 121.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the

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individual has possession of a select agent or toxin (e.g., carries, uses, or manipulates) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) A person with valid approval from the HHS Secretary or Administrator to have access to select agents or toxins may request, through his or her Responsible Official, that the HHS Secretary or Administrator provide their approved access status to another registered individual or entity for a specified period of time.

(f) An individual's security risk assessment may be expedited upon written request by the responsible official and a showing of good cause (e.g., public health or agricultural emergencies, national security, or a short-term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(g) An individual's access approval for VS select agents or toxins may be denied, limited, or revoked if:

(1) The individual is within any of the categories described in 18 U.S.C. 175b;

(2) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) It is determined that such action is necessary to protect animal health or animal products.

(h) For overlap select agents or toxins, an individual's access approval will be denied or revoked if the individual is within any of the categories described in 18 U.S.C. 175b. An individual's access approval may be denied,

limited, or revoked for the reasons set forth in paragraphs (f)(2) through (f)(3) of this section.

(i) An individual may appeal the Administrator's decision to deny, limit, or revoke access approval under § 121.20.

(j) Access approval is valid for a maximum of 3 years.

(k) The responsible official must immediately notify APHIS or CDC when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

[70 FR 13284, Mar. 18, 2005, as amended at 77 FR 61079, Oct. 5, 2012]

### § 121.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control;

(2) Contain provisions for the control of access to select agents and toxins, including the safeguarding of animals or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

(3) Contain provisions for routine cleaning, maintenance, and repairs;

(4) Establish procedures for removing unauthorized or suspicious persons;

(5) Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes;

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or